

# EXHIBIT C



**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

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) MDL No.1456  
) Master File No. 01-CV-12257-PBS  
)  
) Judge Patti B. Saris

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THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-A-Care of  
the Florida Keys, Inc., et al. v. Boehringer  
Ingelheim Corporation, et al.*, Civil Action No.  
07-10248-PBS

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**ROXANE DEFENDANTS' FIRST SET OF REQUESTS  
FOR PRODUCTION OF DOCUMENTS  
AND TANGIBLE THINGS TO PLAINTIFFS**

Defendants Boehringer Ingelheim Corp., Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., and Roxane Laboratories, Inc. (collectively, the "Roxane Defendants"), pursuant to Rule 34 of the Federal Rules of Civil Procedure and the Local Rules, request that Plaintiff the United States of America and Relator Ven-A-Care of the Florida Keys, Inc. (collectively, "Plaintiffs") produce the documents requested herein by making them available for inspection and copying at the offices of Kirkland & Ellis LLP, 200 East Randolph Drive, Chicago, Illinois, 60601, or at such other place and in such manner as may be mutually agreed upon between counsel for the parties, within thirty (30) days from the date of service of these Requests.

## **DEFINITIONS**

The Roxane Defendants hereby incorporate the definitions provided in Local Rule

26.5(c). The following terms used in these requests, whether or not capitalized, shall have the following meanings:

1. “AMP” or “Average Manufacturer Price” shall have the meaning set forth in 42 U.S.C. § 1396r-8(k)(1).

2. “AWP” or “Average Wholesale Price” shall have the meaning ascribed to those terms in paragraphs 51 and 57 of the Complaint.

3. “Between,” when used in regard to the transmittal of information, shall mean any communication by, to, from, or among any individual(s) or entity(ies) specified in a particular request.

4. “CHAMPUS” means Civilian Health and Medical Program of the Uniformed Services and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

5. “CMS” means “Centers for Medicare and Medicaid Services,” its predecessor agencies and all branches, regional offices, agencies, committees, or departments, including the administrators, staff, employees, agents, including but not limited to carriers, consultants, accountants, or attorneys of any of the foregoing. “CMS” and “HCFA” refer to the same agency and are used interchangeably throughout these Requests.

6. “Complaint” means and refers to the Complaint filed on or around January 18, 2007 by which the United States of America intervened in certain portions in Case No. 00-CV-10698 (severed to a new case number, 07-10248-PBS), pending in the United States District Court for the District of Massachusetts.

7. “Congress” means the legislative branch of the U.S. Government, individual members of Congress, and any congressional committees or subcommittees, including but not limited to the Congressional Budget Office, Senate Finance Committee, the House Committee on Ways and Means, the House Committee on Energy and Commerce, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, and all other branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

8. “Customers” has the meaning ascribed to that term in paragraph 3 of the Complaint.

9. “Defendants” refers to the Roxane Defendants.

10. “DMERC” or “Durable Medical Equipment Regional Carrier” mean and refer to any insurance company or other entity that has contracted with HCFA or CMS to process Medicare Part B claims submitted by any Provider for durable medical equipment or any drugs administered via durable medical equipment, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

11. “DOJ” means the United States Department of Justice and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

12. “Equivalent Drugs” means those drugs that contain the same active chemical compound or are considered to be therapeutically equivalent to the Subject Drugs.

13. “FSS” means and refers to the “Federal Supply Schedule” and shall have the meaning ascribed to that program pursuant to 41 U.S.C. § 259(b)(3)(A).

14. “FUL” means the Federal Upper Limit, the ceiling established by the U.S. Government for reimbursement of certain drugs dispensed to Medicaid beneficiaries. *See* 42 CFR § 447.332.

15. “GAO” means General Accounting Office and all its employees, agents, attorneys, agencies, committees, or affiliates.

16. “HCFA” means the United States Health Care Financing Association, its predecessor and successor agencies and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing. “CMS” and “HCFA” refer to the same agency and are used interchangeably throughout these Requests.

17. “HHS” means the United States Department of Health and Human Services and all its employees, agents, attorneys, agencies, committees, or affiliates.

18. “HHS-OIG” means the Office of Inspector General for HHS and all its employees, agents, attorneys, agencies, committees, or affiliates.

19. “Manufacturer” shall have the meaning set forth in 42 U.S.C. § 1396r-8.

20. “Medicaid” means and refers to the jointly-funded Federal-State health insurance program enacted in 1965 as an amendment to the Social Security Act to pay for the costs of certain medical services.

21. “Medicaid Intermediary” means and refers to any insurance company or other entity that has contracted with any State Medicaid Program to process claims for reimbursement of drugs, develop preferred drug lists, provide guidance on changes to reimbursement methodologies, or provide advice on cost savings, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

22. “Medicaid Drug Rebate Program” means and refers to the program established by the Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8, as amended by the Veterans Health Act of 1992, whereby drug manufacturers have national drug rebate agreements with HHS and a pricing agreement with HHS for the Public Health Service Section 340B Drug Pricing Program.

23. “Medicare” means and refers to the Federal program enacted in 1965 under Title XVIII of the Social Security Act to pay for the costs of certain medical services.

24. “Medicare Carrier” means and refers to any insurance company or other entity, including its administrators, staff, employees, agents, consultants, accountants, or attorneys, that has contracted with HCFA or CMS to process claims submitted under Part B of the Medicare program by any Provider.

25. “MFCU” means and refers to individual state Medicaid Fraud Control Units, including their administrators, staff, employees, agents, consultants, accountants, or attorneys.

26. “MedPac” means Medicare Payment Advisory Commission and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

27. “NAMFCU” means National Association of Medicaid Fraud Control Units and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

28. “NDC” means “National Drug Code,” the code set maintained by the Food and Drug Administration and adopted by the federal Secretary of Health and Human Services as the standard for reporting drugs and biologicals on standard transactions.

29. “New York Counties FUL Drugs” refers to the following drugs: enalapril maleate (20 mg tablet), lorazepam (1 mg tablet), klonopin (0.5 mg tablet), albuterol (90 mcg inhaler and 0.83 mg/ml solution), metoprolol (100 mg tablet), cefadroxil (500 mg tablets and capsule), ranitidine (150 mg tablet), and isosorbide mononitrate (60 mg tablet).

30. “OMB” means the Office of Management and Budget and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

31. “OPA” means the Office of Pharmacy Affairs, the previous name of the PAB, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

32. “PAB” means the Pharmacy Affairs Branch, which administers the Public Health Service 340B Drug Discount Program, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

33. “Plaintiffs” refers to the United States of America and Ven-A-Care.

34. “Provider” or “Providers” means and refers to any and all persons or entities that render health care services, including but not limited to pharmacists, physicians, nurses, nurse practitioners, physicians’ assistants, specialty pharmacies, nursing home personnel, laboratory technicians, x-ray and other medical equipment technicians, and other hospital or physician office personnel.

35. “PSSC” means Pharmacy Services Support Center, which provides assistance to the PAB in administering the Public Health Service 340B Drug Discount Program, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

36. “Relating” or “relate to” means refer to, regard, concern, describe, explain, state, evidence, record, constitute, pertain to, reflect, comprise, contain, embody, mention, show, support, contradict, and discuss, whether directly or indirectly, as required by the context to bring within the scope of the requests in this request for production of documents any documents that might be deemed outside their scope by another construction.

37. “Relator” refers to Ven-A-Care.

38. “Relevant Claim Period” shall refer to the entire period for which Plaintiffs are seeking damages or penalties. *See* paragraph 58 of the Complaint.

39. “Roxane” means Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc., named as defendants in the present matter, and any of their past or present officials, officers, representatives, agents, assigns, attorneys, employees, divisions, or departments, and all other persons or entities acting or purporting to act on their behalf or under their control.

40. “Roxane Defendants” means, collectively, Boehringer Ingelheim Corp., Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., and Roxane Laboratories, Inc., named as defendants in the present matter, and any of their past or present officials, officers, representatives, agents, assigns, attorneys, employees, divisions, or departments, and all other persons or entities acting or purporting to act on their behalf or under their control.

41. “State Medicaid Program” means the state agency responsible for carrying out the Medicaid Program in any particular state and all branches, agencies, committees, or departments, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing.

42. “Subject Drugs” means and refers to those drugs and NDCs listed in Exhibits A and B of the Complaint.

43. “U.S. Government” means and refers to the all legislative and executive branches, agencies, departments, or committees of the United States Government, including the administrators, staff, employees, agents, consultants, accountants, or attorneys of any of the foregoing. U.S. Government includes but is not limited to CMS/HCFA, Congress, Department of Commerce, Department of Defense, DOJ, HHS, HHS-OIG, GAO, MedPac, OMB, OPA/PAB, PSSC, VA and any other agency, department, or committee of the U.S. Government that Plaintiff knows or believes has materials discoverable in this litigation.

44. “VA” means the United States Department of Veterans Affairs, including its administrators, staff, employees, agents, consultants, accountants, or attorneys.

45. “Ven-A-Care” means Ven-A-Care of the Florida Keys, Inc., a corporation organized under the laws of Florida, and all predecessor or successor corporations, and any of its past or present officials, officers, representatives, agents, assigns, attorneys, employees, divisions, departments, agencies, affiliates, subsidiaries, and all other persons or entities acting or purporting to act on its behalf or under its control.

46. “Ven-A-Care Qui Tam Complaint” refers to the Complaint filed under seal in the United States District Court for the District of Massachusetts, Case No. 00-CV-10698, including all amendments.

47. “WAC” or “Wholesale Acquisition Cost” shall have the meaning ascribed to that term in paragraph 51 of the Complaint.

48. “You” and “Your” means and refers to the United States of America or Ven-A-Care, where appropriate.

49. “340B Provider” means and refers to any provider described in Section 340B of the Public Health Act, 42 U.S.C. § 256b.

50. The terms “and” and “or” shall mean “and/or.”

51. Any word written in the singular shall include the plural and vice versa.

52. In case of doubt as to the scope of a clause including “and,” “or,” “any,” “all,” “each,” and “every,” the intended meaning is inclusive rather than exclusive.

### **INSTRUCTIONS**

1. All requests directed to Plaintiff United States of America are not limited to documents in the possession of the United States Department of Health and Human Services (“HHS”) or the central and regional offices of the Centers for Medicare & Medicaid Services (“CMS”), but include all responsive documents in the possession of the U.S. Government’s executive, administrative, and legislative offices and agencies, including but not limited to those agencies and departments specified in the above definition of “U.S. Government,” as well as all DMERCs, Medicare Carriers, and Medicaid Intermediaries, who served as agents of the U.S. Government throughout times relevant to the Complaint. In addition to these agencies, departments, and entities, Plaintiff is requested to search for and produce responsive documents from all other agencies or departments of the U.S. Government that Plaintiff has reason to believe may have documents responsive to these requests. In light of the short time available for fact discovery, Plaintiff is requested to inform counsel for Roxane immediately if it is unwilling to coordinate the search for and production of responsive documents to all such agencies, departments, or entities (*i.e.*, please do not wait until the deadline for responding to these requests).

2. ***Time Frame.*** Unless otherwise specified, these requests seek Documents that were prepared during, or relate to, the Relevant Claim Period ***or*** that correspond to the events, reports, laws, determinations, or documents referred to in particular requests.

3. When an objection is made to any request or any subpart thereof, state with specificity the part or subpart of the document request considered to be objectionable and all grounds for the objection.

4. Each request for documents seeks production of the document in its entirety, without abbreviation or redaction, including all attachments or other matters affixed thereto.

5. With respect to each document that is withheld from production on the basis of any privilege, or any portion of any document that has been redacted on the basis of any privilege in connection with the production of a document, provide a statement setting forth:

- (a) its date;
- (b) its title;
- (c) its author;
- (d) its addressee;
- (e) the identify of each person who received and/or saw the original or any copy of such document
- (f) the specific privilege under which it is withheld;
- (g) its general subject matter;
- (h) its present custodian; and
- (i) description of it that you contend is adequate to support your contention that it is privileged.

6. With respect to any conversation for which a privilege is being asserted, identify by stating the following:

- (a) when and where the conversation occurred;
- (b) the name, title and job or position of each person who was present at or during the conversation whether or not such conversation was in person or by telephone;
- (c) a brief description of the conversation's subject matter;
- (d) the statute, rule or decision that is claimed to give rise to the privilege; and
- (e) the name, title and job or position of all persons on whose behalf the privilege is asserted.

7. All documents are to be produced as they are kept in the usual course of business, their relative order in such files, and how such files were maintained. In accordance with the case management order in this case, all electronic files should be produced in a format to be agreed upon by the parties.



**DOCUMENTS REQUESTED FROM PLAINTIFF UNITED STATES OF AMERICA**

1. All documents received by the U.S. Government pursuant to subpoenas or informal document requests related to any of the Subject Drugs or any of the claims in this litigation.

2. All Documents responsive to any Requests for Production of Documents served by Defendant Abbott Laboratories, Inc. or Defendant Dey, Inc. on the U.S. Government in the matters of *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, formerly Civil Action No. 06-CV-21303-ASG (S.D. Fla.), presently part of MDL No. 1456, Civil Action No. 06-11337-PBS (the “DOJ-Abbott Litigation”), and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc. et al.*, also presently part of MDL No. 1456, Civil Acton No. 05-11084-PBS (the “DOJ-Dey Litigation”).

3. Complete claims data, including any annual, quarterly, or other periodic summaries relating to the claims data, for all the Subject Drugs during the Relevant Claim Period for every Medicare and Medicaid transaction for which the Plaintiffs seek recovery. This data shall be submitted in electronic form in a format to be agreed upon by the parties pursuant to the case management order in this case.

4. For all periods within the Relevant Claim Period, all documents relating to how DMERCs or Medicare Carriers determined the payment amount for the Subject Drugs.

5. For each quarter during the Relevant Claim Period, all documents relating to the calculation of each FUL applicable to the Subject Drugs, the Equivalent Drugs, or the New York Counties FUL Drugs, including, but not limited to, documents sufficient to show how DMERCs, Medicare Carriers, or Medicaid Intermediaries calculated any FUL applicable to the Subject Drugs, the Equivalent Drugs, or the New York Counties FUL Drugs.

6. All documents relating to the determination of whether or not to set a FUL for any of the Subject Drugs, the Equivalent Drugs, or the New York Counties FUL Drugs during the Relevant Claim Period.

7. All documents showing the FUL schedules relating to the Relevant Claim Period.

8. All documents relating to any State Medicaid Program’s failure to use FUL as a basis of payment for the Subject Drugs, the Equivalent Drugs, or the New York Counties FUL Drugs when a FUL had been established for these drugs.

9. All documents relating to communications between CMS and any state or other entity concerning the FUL applicable to the Subject Drugs, the Equivalent Drugs, or the New York Counties FUL Drugs.

10. From January 1, 1965 to the end of the Relevant Claim Period, all Documents relating to any report, memorandum, audit, study, analysis, or survey (whether implemented, started, completed or not) concerning (i) the methodologies, policies, and procedures to be used in determining reimbursement for drugs under Medicare Part B or Medicaid, (ii) drug pricing, or (iii) the acquisition costs of Providers for drugs, including but not limited to the reports included on the attached Exhibit A.

11. For the Subject Drugs and Equivalent Drugs, all Communications concerning the reporting of AMP in connection with the Medicaid Drug Rebate Program between and among Manufacturers, the U.S. Government, any State Medicaid Program, or any DMERC, Medicare Carrier, or Medicaid Intermediary, as well as Documents sufficient to identify which Persons within the U.S. Government received AMP information for the Subject Drugs and Equivalent Drugs.

12. From January 1, 1990 to the end of the Relevant Claim Period, all Communications between CMS/HCFA, HHS, or HHS-OIG and VA, CHAMPUS/Tricare Department of Defense, or any 340B Provider concerning the payment, purchase price, or expenditure of VA, CHAMPUS/Tricare, Department of Defense, or any 340B Provider for the Subject Drugs.

13. From January 1, 1990 to the end of the Relevant Claim Period, copies of all Federal Supply Schedules listing the Subject Drugs, as well as all documents relating to the prices the VA, Department of Defense or any 340B Provider paid to obtain the Subject Drugs.

14. Documents sufficient to identify the amounts received each year by each state under the Medicaid Drug Rebate Program for the Subject Drugs.

15. The disclosure statement filed by Ven-A-Care pursuant to 31 U.S.C. § 3730(b)(2), as well as Documents sufficient to identify which Persons within the U.S. Government, any State Medicaid program, NAMFCU, any MFCU, any DMERC, any Medicare Carrier, and/or any Medicaid Intermediary received either that document or the Ven-A-Care Qui Tam Complaint, and when and under what circumstances such Persons received those documents.

16. All pleadings or other Documents filed under seal in *United States ex rel. Ven-A-Care of the Florida Keys, Inc. vs. Roxane Laboratories, Inc. et al.*, Case No. 00-CV-10698 (D. Mass.), beginning with the Ven-A-Care Qui Tam Complaint filed on April 10, 2000.

17. All Documents concerning any notice of or information about this litigation that was circulated to any official, department, agency, or employee of the U.S. Government, any state government, or any member of Congress.

18. All Documents sufficient to identify all DMERCs and Medicare Carriers during the Relevant Claim Period, as well as the time period and geographical areas for which they served, including their names, addresses, and contact information.

19. Documents sufficient to identify all Medicaid Intermediaries and any other vendor used by State Medicaid Programs in connection with the payment of drugs, as well as the time period and geographical areas for which they served, including their names, addresses, and contact information.

20. Documents sufficient to identify the corporate structure as well as documents sufficient to identify the names, titles, and/or job descriptions of employees of all DMERCs, Medicare Carriers, and Medicare Intermediaries during the period that they acted as DMERCs, Medicare Carriers, or Medicare Intermediaries.

21. From January 1, 1990 to the end of the Relevant Claim Period, all Communications between any DMERC, Medicare Carrier, or Medicare Intermediary, and any other DMERC, Medicare Carrier, Medicaid Intermediary, Provider, CMS office or official, or OIG official concerning AWP, WAC, AMP, Direct price and/or List price, or the methodology to be used in calculating payment for drugs under Medicare Part B.

#### **DOCUMENTS REQUESTED FROM RELATOR VEN-A-CARE**

22. All Documents responsive to any Requests for Production of Documents served by Defendant Abbott Laboratories, Inc. or Defendant Dey, Inc. on Ven-A-Care in the matters of *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, formerly Civil Action No. 06-CV-21303-ASG (S.D. Fla.), presently part of MDL No. 1456, Civil Action No. 06-11337-PBS (the “DOJ-Abbott Litigation”), and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc. et al.*, also presently part of MDL No. 1456, Civil Action No. 05-11084-PBS (the “DOJ-Dey Litigation”).

23. From any time period, all Documents relating to Ven-A-Care’s participation in or contribution to any report, memorandum, audit, study, analysis, or survey (whether completed or not) concerning (i) the methodologies, policies, and procedures to be used in determining reimbursement for drugs under Medicare Part B or Medicaid, (ii) drug pricing, or (iii) the acquisition costs of Providers for drugs, including but not limited to the reports included on the attached Exhibit A.

24. All Documents concerning:

- (a) the price Ven-A-Care paid for the Subject Drugs or the Equivalent Drugs;
- (b) all claims for payment submitted by Ven-A-Care to Medicare Part B or Medicaid for the Subject Drugs or the Equivalent Drugs;
- (c) all payments made to Ven-A-Care by Medicare Part B or Medicaid for the Subject Drugs or the Equivalent Drugs;
- (d) any repayments made by Ven-A-Care to Medicare Part B or Medicaid relating to the Subject Drugs or the Equivalent Drugs; and
- (e) all contracts or agreements between Roxane and Ven-A-Care for the Subject Drugs.

25. Documents sufficient to show Ven-A-Care's costs in providing services of any type to Medicare or Medicaid beneficiaries, including the extent to which payment for drugs was used to offset that cost.

26. All pleadings or other Documents filed under seal in *United States ex rel. Ven-A-Care of the Florida Keys, Inc. vs. Roxane Laboratories, Inc. et al.*, Case No. 00-CV-10698 (D. Mass.), beginning with the Ven-A-Care Qui Tam Complaint filed on April 10, 2000.

27. From any time period, all disclosure statements filed by Ven-A-Care in any state or federal qui tam action relating to reimbursement of drugs under Medicare Part B or Medicaid.

Dated: November 7, 2007

Respectfully submitted,

/s/ Eric T. Gortner  
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*On behalf of Defendants Boehringer Ingelheim Corp., Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., and Roxane Laboratories, Inc.*

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 7, 2007, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ Eric T. Gortner

Eric T. Gortner



# Exhibit A

## **SELECT GOVERNMENT REPORTS AND STUDIES**

1. Task Force on Prescription Drugs, the Office of Secretary, United States Department of Health, Education and Welfare – The Drug Makers and the Drug Distributor (Dec. 1968)
2. Task Force on Prescription Drugs, the Office of Secretary, United States Department of Health, Education and Welfare – Final Report (Feb. 1969)
3. GAO-RPT, “Programs to Control Prescription Drug Costs Under Medicaid and Medicare Could Be Strengthened” (GAO/HRD-81-36, Dec. 31, 1980)
4. HHS-OIG, “Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs” (Sep. 1, 1984)
5. HCFA (Region IX), “EAC Survey Report, Hawaii Medicaid Program, EAC Patrol Initiative” (1986)
6. HHS-OIG, “Changes to the Maximum Allowable Cost Medicaid Drug Limit Could Save Millions (CAN 08-60203, Aug. 15, 1986)
7. GAO-RPT, “Medicare Prescription Drug Issues” (GAO/PEMD-87-20, Jul. 16, 1987)
8. Majority Staff Report, Special Committee of Aging, United States Senate – “Prescription Drug Prices: Are We Getting Our Money’s Worth?” (S. Rep. 101-49, 1989)
9. HHS-OIG, “Use of Average Wholesale Price in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program” (A-06-89-0037, Oct. 1989)
10. HHS-OIG, “Strategies to Reduce Medicaid Drug Expenditures” (Draft Report) (OEI-12-90-00800, Sep. 6, 1990)
11. HHS-OIG, “Strategies to Reduce Medicaid Drug Expenditure” (OEI-12-90-00800, Mar. 1, 1991)
12. HHS-OIG, “Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in the United States and Canada” (OEI-03-91-000470, Aug. 1, 1991)
13. HHS-OIG, “Promotion of Prescription Drugs Through Payments and Gifts” (OEI-01-90-00480, Aug. 1, 1991)
14. HHS-OIG, “Medicaid Drug Rebates - Improvements Needed in the Health Care Financing Administration's Procedures to Implement the Medicaid Drug Rebate Program” (A-06-91-00102, Apr. 23, 1992)
15. HHS-OIG, “Medicaid Drug Rebates - Inaccurate Reporting of Medicaid Drug Data by Pharmacists” (A-06-91-00056, Jun. 5, 1992)

16. HHS-OIG, "Prescription Drug Promotion Involving Payments and Gifts: Physicians' Perspectives" (OEI-01-90-00481, Jul. 1, 1992)
17. GAO-RPT, "Prescription Drugs - Changes in Prices for Selected Drugs" (GAO/HRD-92-128, Aug. 24, 1992)
18. HHS-OIG, "Medicaid Drug Rebates - The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program" (A-06-91-00092, Nov. 1992)
19. HHS-OIG, "Physicians' Costs for Chemotherapy Drugs" (A-02-91-01049, Nov. 6, 1992)
20. GAO-RPT, "Medicaid - Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland" (GAO/HRD-93-55FS, Mar. 18, 1993)
21. HHS-OIG, "Review of Management Controls Over the Medicaid Prescription Drug Rebate Program" (A-06-92-00029, Jun. 9, 1993)
22. HHS-OIG, "Audit of the Arkansas Department of Human Services' Medicaid Prescription Drug Rebate Program" (A-06-93-00003, Jul. 30, 1993)
23. National Technical Information Service (U.S. Dep't of Commerce), "Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients," Systemetrics, Inc., (National Technical Information Service (PB94-187689, Aug. 1993) (Kathleen Adams, Norma Gavin and David Kreling, authors)
24. HHS-OIG, "Elimination of the Weighted Average Manufacturer Price Provisions of the Medicaid Outpatient Prescription Drug Rebate Program" (A-06-93-00070, Dec. 28, 1993)
25. GAO-RPT, "Prescription Drugs - Companies Typically Charge More in the United States Than in the United Kingdom" (GAO/HEHS-94-29, Jan. 12, 1994)
26. GAO-RPT, "Prescription Drugs - Spending Controls in Four European Countries" (GAO/HEHS-94-30, May 17, 1994)
27. HHS, "Report to Congress - Pharmacy Reimbursement Rates: Their Adequacy and Impact on Medicaid Beneficiaries" (HCFA Pub. No. 03353, Jun. 1994)
28. HHS-OIG, "Medicaid Program Savings Through the Use of Therapeutically Equivalent Generic Drugs" (A-06-93-00008, Jul. 7, 1994)
29. HHS-OIG, "Medicaid Drug Use Review Programs - Lessons Learned by States" (OEI-01-92-00800, May 1, 1995)
30. GAO-RPT, "Medicare - Excessive Payments for Medical Supplies Continue Despite Improvements" (GAO/HEHS-95-171, Aug. 8, 1995)



31. HHS-OIG, "Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment" (A-06-92-00079, Aug. 14, 1995)
32. HHS-OIG, "Medicare Payments for Nebulizer Drugs" (OEI-03-94-00390, Feb. 1, 1996)
33. HHS-OIG, "Appropriateness of Medicare Prescription Drug Allowances" (OEI-03-95-00420, May 1, 1996)
34. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062, May 31, 1996)
35. HHS-OIG, "A Comparison of Albuterol Sulfate Prices" (OEI-03-94-00392, Jun. 1, 1996)
36. HHS-OIG, "Suppliers' Acquisition Costs for Albuterol Sulfate" (OEI-03-94-00393, Jun. 1, 1996)
37. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services" (A-06-95-00068, Jul. 11, 1996)
38. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Florida Agency for Health Administration" (A-06-95-00065, Aug. 13, 1996)
39. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Resources" (A-06-95-00071, Sep. 4, 1996)
40. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Delaware Department of Health and Human Service" (A-06-95-00063, Sep. 12, 1996)
41. GAO-RPT, "Medicare Drugs and Nutrient Prices" (Letter from Wm. Scanlon to Rep. Pete Stark) (GAO/HEHS-97-22R, Oct. 11, 1996)
42. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Medical Assistance Services" (A-06-95-00072, Nov. 21, 1996)
43. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the New Jersey Department of Human Services" (A-06-95-00070, Dec. 6, 1996)
44. HHS-OIG, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Nebraska Department of Social Services" (A-06-95-00069, Dec. 24, 1996)

45. HHS-OIG, “Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services” (A-06-95-00067, Jan. 21, 1997)
46. HHS-OIG, “Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services” (A-06-95-00064, Jan. 31, 1997)
47. HHS-OIG, “Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene” (A-06-95-00066, Feb. 12, 1997)
48. HHS-OIG, “Questionable Practices Involving Nebulizer Drug Therapy” (OEI-03-94-00391, Mar. 1, 1997)
49. HHS-OIG, “Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs” (A-06-96-00030, Apr. 10, 1997)
50. GAO-RPT, “Drug Prices - Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain” (GAO/HEHS-97-60, Jun. 11, 1997)
51. HHS-OIG, “Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products” (A-06-97-00011, Aug. 4, 1997)
52. HHS-OIG, “Excessive Medicare Payments for Prescription Drugs” (OEI-03-97-00290, Dec. 1997)
53. HHS-OIG, “Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs” (A-06-97-00052, May 8, 1998)
54. GAO-RPT, “Medicare - Need to Overhaul Costly Payment System for Medical Equipment and Supplies” (GAO/HEHS-98-102, May 12, 1998)
55. HHS-OIG, “Impact of High Priced Generic Drugs on Medicare and Medicaid” (OEI-03-97-00510, Jul. 1, 1998)
56. HHS-OIG, “Audit of Utilization of the Public Health Service 340B Drug Pricing Program” (A-01-98-01500, Jul. 6, 1998)
57. HHS-OIG, “Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs” (OEI-03-97-00293, Nov. 1998)
58. HHS-OIG, “OIG’s Partnership Plan – Utah Division of Health Care Financing Reports on Medicaid Pharmacy Acquisition Costs of Brand Name and Generic Drugs” (A-06-99-00035 and A-06-99-00036, May 4, 1999)
59. GAO-RPT, “Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications” (GAO/T-HEHS/AIMD-00-99, Feb. 15, 2000)

60. GAO-RPT, "Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications" (GAO/T-HEHS/AIMD-00-100, Feb. 16, 2000)
61. GAO-RPT, "Prescription Drugs – Expanding Access to Federal Prices Could Cause Other Price Changes" (GAO/HEHS-00-118, Aug. 7, 2000)
62. GAO-RPT, "United States Prescription Drug Pricing and Reimbursement Policies" (John Hansen, GAO) (Oct. 1, 2000)
63. GAO-RPT, "Drug Prices Paid by DOD and VA are, On Average, Lower Than Those Certified to HCFA as Best Price" (GAO-01-175R, Letter from R.H. Hast, GAO Office of Special Investigations to Rep. H. Waxman, Oct. 31, 2000)
64. HHS-OIG, "Medicare Reimbursement of Prescription Drugs" (OEI-03-00-00310, Jan. 2001)
65. HHS-OIG, "Cost Containment of Medicaid HIV/AIDS Drug Expenditures" (OEI-05-99-00611, Jul. 2001)
66. HHS-OIG, "Medicaid Pharmacy – Actual Acquisition Price of Brand Name Prescription Drug Products" (A-06-00-0023, Aug. 10, 2001)
67. HHS-OIG, "Medicaid's Use of Revised Average Wholesale Prices" (OEI-03-01-00010, Sep. 2001)
68. GAO-RPT, "Medicare-Payments for Covered Outpatient Drugs Exceed Providers' Costs" (GAO-01-1118, Sept. 21, 2001)
69. GAO-RPT, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices" (GAO-01-1142T, Sep. 21, 2001)
70. GAO-RPT, "Medicare Physician Fee Schedule - Practice Expense Payments to Oncologists Indicate Need for Overall Refinements" (GAO-02-53, Oct. 31, 2001)
71. HHS-OIG, "Review of Pharmacy Acquisition Cost for Drugs Under Medicaid Prescription Drug Program of West Virginia Department of Health" (A-06-01-00007, Dec. 31, 2001)
72. The report prepared for CMS by PriceWaterhouseCoopers entitled, "A Study of Pharmaceutical Benefit Management" (Jun. 2001), referenced at 67 Fed. Reg. 10,285 (Mar. 6, 2002)
73. GAO-RPT, "Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices" (GAO-02-531T, Mar. 14, 2002)
74. HHS-OIG, "Excessive Medicare Reimbursement for Ipratropium Bromide" (OEI-03-01-00411, Mar. 2002)

75. HHS-OIG, “Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products” (A-06-01-00053, Mar. 14, 2002)
76. GAO-RPT, “Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs” (GAO-02-833T, Jun. 12, 2002)
77. HHS-OIG, “Update: Excessive Medicare Reimbursement for Ipratropium Bromide” (OEI-03-03-00520, Jan. 2004)
78. HHS-OIG, “Omission of Drugs from the Federal Upper Limit List in 2001” (OEI-03-02-00670, Feb. 2004)
79. HHS-OIG, “Variation in State Medicaid Drug Prices” (OEI-05-02-00681, Sep. 2004)
80. HHS-OIG, “Addition of Qualified Drugs to the Medicaid Federal Upper Limit List” (OEI-03-04-00320, Dec. 2004)
81. GAO-RPT, “Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States” (GAO-05-102, Feb. 4, 2005)
82. HHS-OIG, “Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices” (OEI-03-05-00110, Jun. 2005)
83. HHS-OIG, “Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price” (OEI-03-05-00200, Jun. 2005)
84. HHS-OIG, “How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List” (OEI-03-05-00350, Sep. 2005)
85. HHS-OIG, “Deficiencies in the Oversight of the 340B Drug Pricing Program” (OEI-05-02-00072, Oct. 2005)
86. HHS-OIG, “Review of 340B Prices” (OEI-05-02-00073, Jul. 2006)
87. GAO-RPT, “Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs” (GAO-07-239R, Dec. 22, 2006)
88. HHS-OIG, “States’ Use of New Drug Pricing Data in the Medicaid Program” (OEI-03-06-00490, Apr. 2007)
89. HHS-OIG, “Examining Fluctuations in Average Manufacturer Prices” (OEI-03-06-00350, May 2007)